SpotOn™ Temperature Monitoring System Model 370

Operator's Manual

(GB) 3M™ SpotOn™ Temperature Monitoring System
• Model 370 • Operator's Manual

(FR) Système de surveillance de la température 3M™ SpotOn™
• Modèle 370 • Manuel d'utilisation

(DE) 3M™ SpotOn™ Temperaturüberwachungssystem
• Modell 370 • Bedienerhandbuch

(IT) 3M™ SpotOn™ Sistema di monitoraggio della temperatura
• Modello 370 • Manuale dell'operatore

(ES) 3M™ SpotOn™ Sistema de control de temperatura
• Modelo 370 • Manual del operador

(NL) 3M™ SpotOn™-temperatuurcontrolesysteem
• Model 370 • Gebruikershandleiding

(SE) 3M™ SpotOn™ Temperaturövervakningssystem
• Modell 370 • Bruksanvisning

(DK) 3M™ SpotOn™ temperaturovervågningssystem
• Model 370 • Brugervejledning

(NO) 3M™ SpotOn™ temperaturovervåkingssystem
• modell 370 • Brukerhåndbok

(FI) 3M™ SpotOn™ -lämpötilanseurantajärjestelmä
• Malli 370 • Käyttöopas

(PT) Sistema de Monitorização da Temperatura 3M™ SpotOn™
• Modelo 370 • Manual do utilizador

3M™ SpotOn™
Temperature Monitoring System

Revision History

Revision	Reason for Change	Pages Affected	Date
370096 A	New Revision - First Release	All	May 2012
370096 B	Languages Added	25-155	May 2012
370096 C	Added specifications and added languages	All	February 2013
202052 A	Update company address	All	May 2013

Operator's Manual
Model 370
3M™ SpotOn™
Temperature Monitoring System

English	**5**
Français	**23**
Deutsch	**47**
Italiano	**71**
Español	**95**
Nederland	**119**
Svenska	**143**
Dansk	**167**
Norsk	**191**
Suomenkielinen	**215**
Português	**239**

GB 3M™ SpotOn™ Temperature Monitoring System
• Model 370 • Operator's Manual

3M™ SpotOn™
Temperature Monitoring System

Table of Contents

Section 1: Introduction **3**
About this manual 3
Intended use 3
Safety information and symbols 3
Proper use and maintenance 6
Read before servicing equipment 6

Section 2: Overview and Operation **7**
Description of the SpotOn temperature monitoring system 7
How does it work? 8
SpotOn control unit 8
SpotOn temperature sensor 8
Back of Control Unit 9
Front of Control Unit 9
Setting up the SpotOn control unit 9
Instructions for use 10
Transferring the patient and sensor 11
Removing the sensor 11
To change temperature unit display (Celsius or Fahrenheit) 12
Shutting down the control unit 12

Section 3: Display Panel **13**
Display screens 13
Start-up 13
Standby 13
Ready 14
Equilibration 14
Running 14
Control unit error 14
Sensor error 14

Section 4: Troubleshooting **15**
On Mode 15
Displays 15
Errors 16

Section 5: General Maintenance, Storage and Service **17**
Cleaning and Disinfecting Procedure 17
Cleaning the control unit and cable 17
Disinfecting the sensor cable 17
Storage 17
Service 17

Section 6: Technical Service and Order Placement 19
When you call for technical support 19
Technical service and order placement 19
USA 19
Outside of the USA 19

Section 7: Specifications 21
Physical characteristics 21
Electrical characteristics 22
Temperature characteristics 22
Performance characteristics 22
Leakage current 22
Environmental conditions 22

Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

Section 1: Introduction

About this manual . . . 3
Intended use . . . 3
Safety information and symbols . . . 3
Explanation of signal word consequences . . . 4
Proper use and maintenance . . . 6
Read before servicing equipment . . . 6

About this manual

This Operator's Manual describes the setup, use, and maintenance of the 3M™ SpotOn™ temperature monitoring system. The SpotOn temperature monitoring system and the manual are to be used by healthcare professionals in clinical environments only. Read and follow all instructions, labeling and accompanying documents supplied with this SpotOn temperature monitoring system. Failure to follow instructions could lead to misuse of the device, device malfunction, or patient injury.

Intended use

Measure, monitor, and trend body temperature of adult and pediatric patients.

Safety information and symbols

Date of manufacture

Manufacturer

Single use only

Container quantity

CAUTION

This system is subject to the European WEEE Directive 2002/96/EC.
This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.

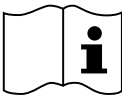
Defibrillation-proof type CF applied part

Class II equipment

Authorized Representative in the European Community

CAUTION: Recycle to avoid environmental contamination
This product contains recyclable parts. For information on recycling - please contact your nearest 3M Service Center for advice.

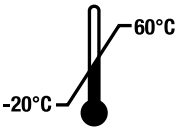
Direct current



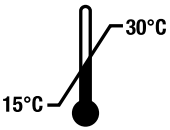
See accompanying documents

Follow instructions for use

Keep dry



Hardware temperature limits



Sensor temperature limits

Explanation of signal word consequences

WARNING: Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION: Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE: Indicates a situation which, if not avoided, could result in property damage only.

WARNINGS

1. To reduce the risks associated with access to critical patient information or equipment:
   - The SpotOn control unit is to be attached to other equipment by authorized service personnel only.
   - Do not re-install or re-locate the SpotOn control unit.
2. To reduce the risks associated with hazardous voltage, fire, and thermal energy hazards:
   - Use ONLY with 3M SpotOn system components (sensors, cables, and power supply). Do not substitute other devices for the SpotOn control unit, sensor, cables, or power supply.
   - Do not use the SpotOn temperature monitoring system (sensor, control unit, cables, or cords) in an MRI environment.
3. To reduce the risks associated with hazardous voltage and fire:
   - Keep power supply visible and accessible at all times. The plug on the power supply serves as the disconnect device. The power outlet shall be as close as practical and shall be easily accessible.
   - Use only the power supply specified for this product and certified for the country of use.
   - Use only a properly grounded power outlet; do not use extension cords or multiple portable socket outlets.
   - Do not allow the power supply to get wet.
   - Do not use the SpotOn control unit when it appears the unit or system components are damaged. Contact 3M Patient Warming technical support at 1-800-733-7775 or 952-947-1200.
   - Do not service or modify the power supply, control unit, cables, sensor, or any part of the 3M SpotOn system. There are no user serviceable parts.
4. To reduce the risks associated with fire:
   - This system is not suitable for use in the presence of a flammable anesthetic mixture with air nitrous oxide.
5. To reduce the risks associate with pressure, and crushed or entangled cords and connectors:
   - Do not allow the patient to lie on any SpotOn sensor cable or connector.
   - Always position cables and cords away from the patient's body.
   - Do not use a headband or other device to secure the SpotOn sensor to the patient.
6. To reduce the risks associated with incorrect system or sensor use:
   - Limit use of the SpotOn temperature sensor to 24 hours. Extended use may compromise skin, cause degradation of material or performance.
   - Avoid exposing the SpotOn temperature sensor, sensor cable, power supply, and control unit to surgical skin surface preparation solutions or other fluids.
   - Use an additional independent thermometer to measure body temperature during intentional hyperthermia or hypothermia therapy.
   - Confirm unanticipated temperature reading with an independent thermometer, if needed.
   - Do not reposition the SpotOn temperature sensor; repositioning may weaken the sensor adhesive, damage the sensor, or compromise the device performance.
   - Avoid placing the sensor in the center of the forehead as this may affect sensor accuracy.
7. To reduce the risks associated with exposure to biohazards:
   - Follow facilities policies and procedures for disposal of contaminated materials.
   - Always perform the decontamination procedure prior to returning the SpotOn temperature monitoring system for service and prior to disposal.
8. To reduce the risks associated with entanglement:
   - Do not leave pediatric patients unattended while using the SpotOn temperature monitoring system.

CAUTIONS

1. To reduce the risks associated with skin maceration:
   - Do not use the sensor on damaged or compromised skin.
2. To reduce the risks associated with cross-contamination:
   - Clean the sensor cable before connecting to a new sensor.
3. To reduce the risks associated with impact and facility medical device damage:
   - Do not use the SpotOn control unit as a handle to transport or to move the device to which it is attached.
   - Do not initiate temperature monitoring unless the SpotOn control unit is safely placed on a hard, flat surface or is securely mounted.
4. To reduce the risks associated with environmental contamination:
   - Follow applicable regulations when disposing of this device or any of its electronic components.

NOTICES

1. The SpotOn temperature monitoring system meets medical electronic interference requirements. If radio frequency interference with other equipment should occur, connect the unit to a different power source.
2. Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.
3. To avoid SpotOn temperature monitoring system damage that may impact performance:
   - Do not store the SpotOn control unit and system components in a wet or damp place.
   - Do not spray cleaning solutions onto the control unit or into the sensor cable connector.
   - Do not immerse the SpotOn temperature monitoring control unit or system components in any liquid or subject them to any sterilization process.
   - Do not use solvents such as acetone or thinner to clean the control unit; avoid abrasive cleaners.
   - Clean control unit exterior with a damp soft cloth and 70% mixture of isopropyl alcohol and water. For full cleaning procedures see “Section 5: General Maintenance, Storage and Service” on page 17.
   - Do not immerse any of the devices or use a dripping wet cloth for cleaning.
4. The SpotOn temperature monitoring sensor is not made with natural latex material.
5. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for injury resulting from the unit being used in conjunction with unapproved system components.

Proper use and maintenance

Arizant Healthcare Inc., a 3M company assumes no responsibility for the reliability, performance, or safety of the temperature monitoring system if the following events occur:

- Modifications or repairs are performed by unqualified personnel.
- The unit is used in a manner other than that described in the Operator’s Manual.
- The unit is installed in an environment that does not meet the appropriate electrical requirements.

Read before servicing equipment

- All repair, calibration, and servicing of this equipment must be performed by 3M Patient Warming.
- There are no user serviceable parts inside the equipment or power supply.

Section 2: Overview and Operation

Description of the SpotOn temperature monitoring system . . . 7
How does it work? . . . 8
Setting up the SpotOn control unit . . . 9
Instructions for use . . . 10
Transferring the patient and sensor . . . 11
Removing the sensor . . . 11
To change temperature unit display (Celsius to Fahrenheit) . . . 12

Description of the SpotOn temperature monitoring system

The SpotOn temperature monitoring system measures the core temperature of the patient. The system is comprised of the SpotOn temperature sensor, which connects to the SpotOn control unit through the sensor cable, a power supply, and an optional monitor cable. For additional sensors, sensor cable, power supply, control unit stand, monitor cable, hook-and-loop, or foam adhesive, contact 3M Patient Warming.

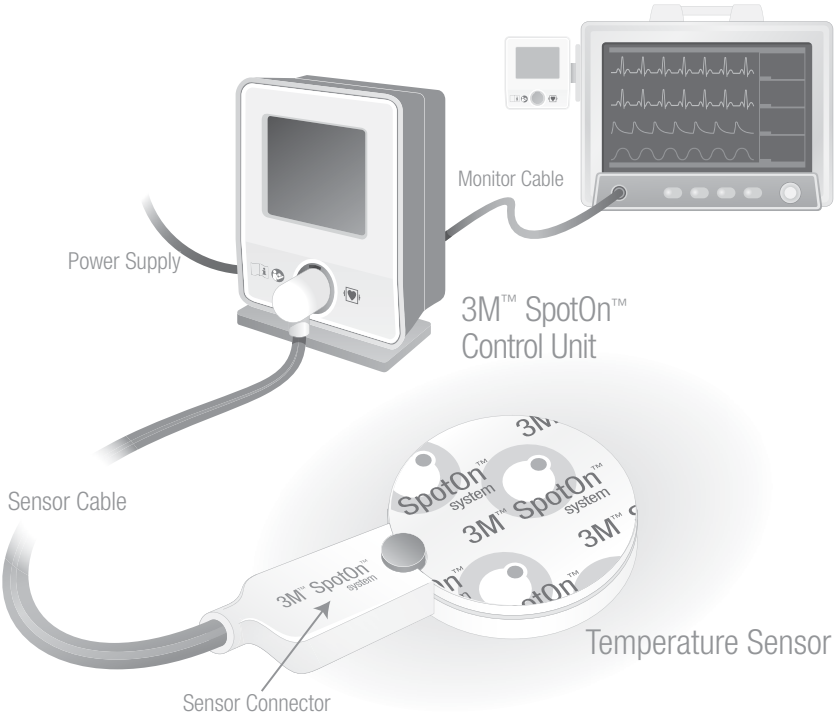


Figure 2: SpotOn Temperature Monitoring System

How does it work?

The SpotOn temperature monitoring system uses zero-heat-flux thermometry to accurately measure a person's core temperature as characterized in Figure 3 below. 1) The SpotOn temperature monitoring system gently warms the sensor creating an isothermal zone under the sensor. 2) Once equilibrated to the core temperature, skin-surface heat loss to the environment is prevented and a zero-heat-flux condition is established. 3) When the temperature sensor reaches equilibrium with the patient's core temperature, the SpotOn control unit displays an accurate, noninvasive measurement of the patient's core temperature.

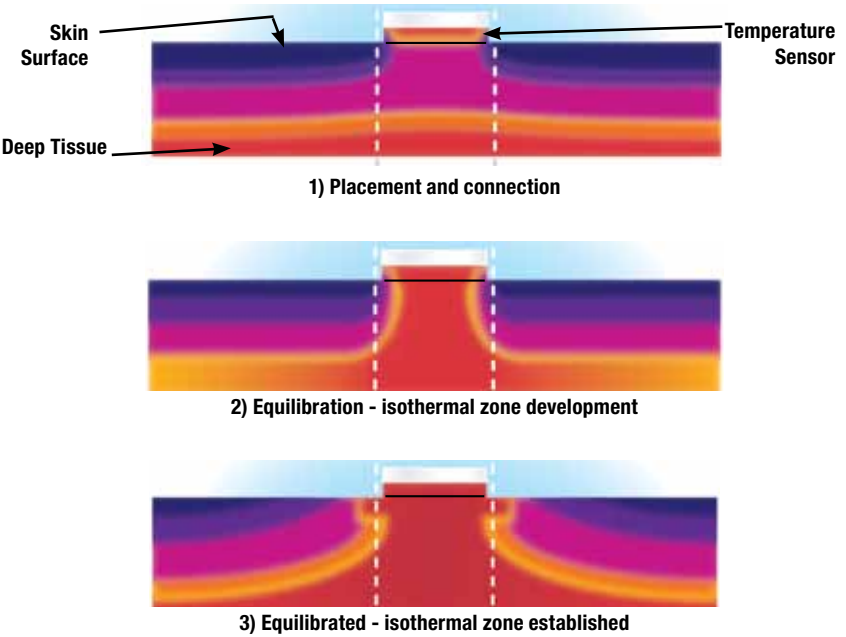


Figure 3: Isothermal tunnel formation with zero-heat-flux technology

SpotOn control unit

The SpotOn control unit displays noninvasive core temperature measurements obtained from the SpotOn temperature sensor. The current temperature is displayed numerically, and previous temperature data is displayed graphically as a temperature trend graph. When the sensor is plugged into the sensor cable, the control unit reads up to the last two hours of stored temperature data and displays the temperature trend graph. Disconnections of the sensor from the sensor cable are indicated by gaps in the temperature trend graph. The current temperature measurement can be continuously transmitted to a patient vital signs monitor through the optional SpotOn monitor cable using a standard YSI-400 type input.

SpotOn temperature sensor

The SpotOn sensor is constructed of two layers of medical grade foam and a flexible circuit which contains a resistive warming circuit, two calibrated thermistors, and nonvolatile memory. The information that generates the temperature trend graph is stored on the SpotOn sensor. If the patient is transferred from one location to another, the SpotOn sensor is disconnected from the SpotOn sensor cable so the sensor is left in place on the patient. The SpotOn sensor may be reconnected to a different SpotOn sensor cable and control unit when the patient arrives at the next point of care. Once the SpotOn sensor is reconnected to the SpotOn sensor cable, the system will begin to reequilibrate and will regenerate the stored temperature trend graph and display the patient's current temperature. The act of disconnecting and reconnecting the SpotOn sensor from the sensor cable is indicated by a gap in the temperature trend graph.

Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

Back of Control Unit

To view information and connections on the back of the control unit, assure that controller is viewed from a distance no further than 15" (38 cm) from the operator.

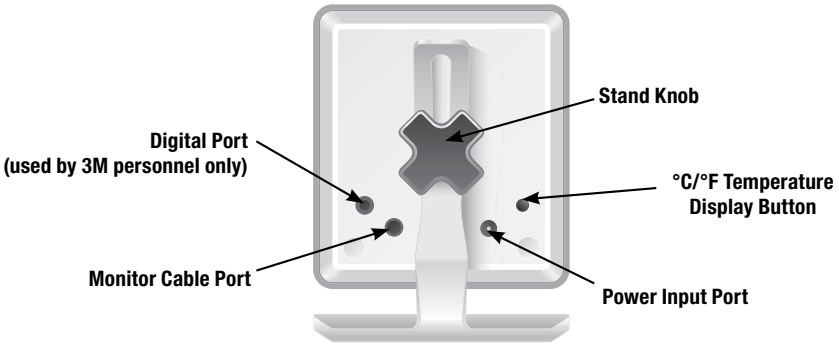


Figure 5: Back of Control Unit

The digital port is used only by 3M Patient Warming personnel for testing purposes and to access variables within the control unit.
The monitor cable port provides a resistance that corresponds to a YSI-400 thermistor at the displayed temperature. It is electrically isolated from the SpotOn control unit.

Front of Control Unit

Figure 6: Front of Control Unit

Setting up the SpotOn control unit

1. The SpotOn control unit must be properly installed and mounted by qualified personnel.
   NOTE: The SpotOn sensor and control unit are suitable for use in the patient environment.
2. Connect the power supply to the back of the SpotOn control unit (see Figure 5: Back of Control Unit).
   Plug the power supply into an appropriate outlet. The standby screen will illuminate.
3. Connect the SpotOn sensor cable to the front of the control unit. See Figure 6: Front of Control Unit for proper orientation and connection.
4. If desired, use the provided monitor cable to connect the SpotOn control unit to the patient monitor
   (see Figure 5: Back of Control Unit).
   NOTE: Temperature input on patient monitor typically labelled T1 or T2.

Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

Instructions for use

1. Ensure the SpotOn system power supply is connected to the back of the control unit and the power supply is plugged into an appropriate outlet. If desired, ensure the provided monitor cable is connected to the back of the SpotOn control unit and to the YSI-400 type input on the patient monitor.
2. Use an alcohol wipe to clean and disinfect the patient's forehead above the orbital ridge. Allow the patient's forehead to completely dry.
3. Connect the SpotOn temperature sensor to the sensor cable connector. Ensure the sensor tab is properly connected and is fully inserted into the sensor cable (Figure 7). The display on the control unit will change to the ready screen (See "Ready" on page 14) once it confirms the sensor connection.

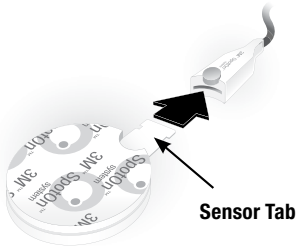


Figure 7: Connect the sensor to the sensor cable

4. Remove backing liners on the SpotOn temperature sensor to expose adhesive (Figure 8).

Figure 8: Remove the backing liners

5. Position the sensor cable away from the patient's face and apply the SpotOn temperature sensor to the patient's forehead above the orbital ridge (Figure 9).

Figure 9: Apply the SpotOn sensor to the patient's forehead

6. Gently press the edge of the sensor to ensure good adhesion with the skin.
   OPTIONAL: Support the SpotOn temperature sensor cable with the provided sensor cable clip.
7. The control unit will sense patient attachment after several seconds and the control unit display will change to the equilibration screen (see "Equilibration" on page 14).
8. The patient's temperature will display on the patient monitor once equilibrium is reached (approximately three minutes).

Transferring the patient and sensor

1. Prior to moving the patient, disconnect the sensor cable from the SpotOn sensor. The sensor may be left on the patient and reconnected to another SpotOn system once patient transfer is complete.
   NOTE: The SpotOn temperature sensor contains integrated memory that captures up to two hours of temperature data in five minute intervals. The SpotOn sensor will retain these temperatures and history.
2. Carefully reconnect a SpotOn sensor cable and control unit to the temperature sensor once transfer is complete.
3. The control unit will sense patient attachment after several seconds and the control unit display will change to the equilibration screen (see "Equilibration" on page 14).
4. The patient's temperature will display on the patient monitor once equilibrium is reached (approximately three minutes).

Removing the sensor

1. Disconnect the sensor cable from the SpotOn temperature sensor. Disconnect the sensor cable clip from the bed or sheet, if used.
2. Starting at the edge of the SpotOn sensor, gently remove the SpotOn temperature sensor from the patient (Figure 10).
   NOTE: Do not use the sensor tab to remove the SpotOn temperature sensor from the patient.
   NOTE: If needed, use an alcohol swab along the sensor edge to help remove the sensor from the patient.
3. Discard the SpotOn sensor and clean the sensor cable. (See Section 5: General Maintenance for details).

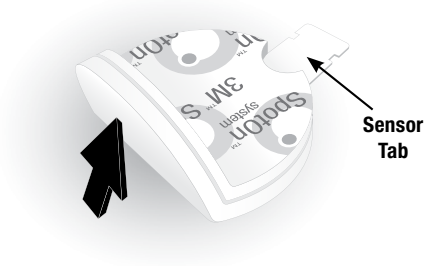


Figure 10: Remove the sensor

Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

To change temperature unit display (Celsius or Fahrenheit)

The SpotOn control unit can display temperature measurements in either Celsius or Fahrenheit. The unit will be factory preset to Celsius.

1. Plug the SpotOn control unit into an appropriate outlet.
2. Push the temperature display button on the back of the control unit to change to the desired measurement scale.
   NOTE: The trend display is always shown in Celsius.

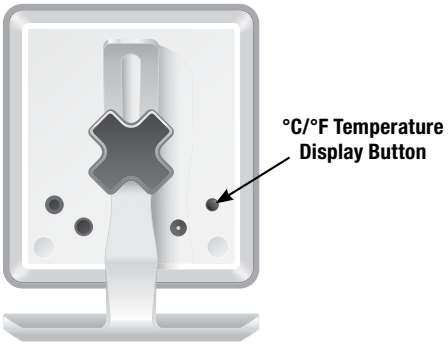


Figure 11: Temperature Display Button

Shutting down the control unit

The plug on the power supply serves as the disconnect device. Turn the control unit on and off by plugging or unplugging the power supply from the wall outlet. The power outlet shall be as close as practical and shall be easily accessible.

Section 3: Display Panel

Display screens 13
Start-up 13
Standby 13
Ready 14
Equilibration 14
Running 14
Control unit error 14
Sensor error 14

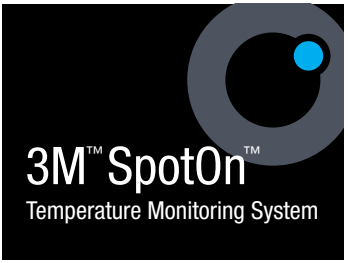
Display screens

Start-up

The start-up screen displays for approximately five seconds when the control unit is initially powered ON. The revision number of the control unit software is also displayed.

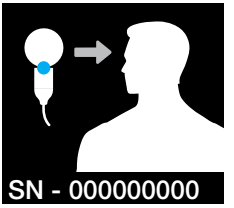
Standby

The SpotOn system graphic is displayed when the unit is not in use.



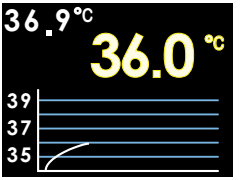
Ready

The ready screen displays the serial number of the SpotOn sensor and indicates the SpotOn sensor cable and sensor are properly attached to the SpotOn control unit. The SpotOn sensor is now ready to be attached to the patient.



Equilibration

A flashing yellow temperature display indicates the sensor has been connected to the patient and to the control unit and is in the process of equilibration. The graph below the temperature output indicates the progress of equilibration. This process will take approximately three minutes.

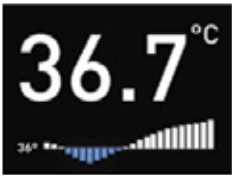


If you see a temperature in the upper left hand corner of the screen, that is the last recorded temperature that has been captured by the sensor on the patient's head. The sensor captures and records a temperature every five minutes.

After the equilibration is complete, the patient's body temperature is displayed on the SpotOn control unit in bold white numbers and can be automatically transmitted to the patient monitor via the monitor cable.

Running

The running screen displays the deep tissue temperature of the patient in white. The trend graph at the bottom of the screen displays the last two hours of the patient's temperature in five minute increments. The bars on the graph will begin filling from the right with the 36°C always visible. The blue bars indicate that the temperature dropped below 36°C (white indicates the temperature is above 36°C).

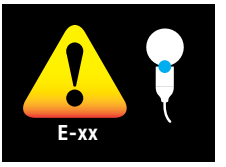


Control unit error

The SpotOn control unit error screen displays when there is a system error. Discontinue use of unit. Contact a biomedical technician.

Sensor error

The sensor error screen displays when there is a temperature sensor or cable error. See "Section 4: Troubleshooting" on page 15 for details.



Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

Section 4: Troubleshooting

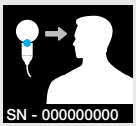
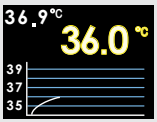
On Mode. 15
Displays. 15
Errors. 16

The following conditions are listed in the order of which troubleshooting actions should be performed.

On Mode

Condition	Cause	Action
Unit does not power up.	Unit is not plugged in, or power supply is not plugged into an appropriate outlet.	Make sure the power supply is plugged into the control unit. Make sure the control unit is plugged into an appropriate power outlet.
	Unit failure.	Contact 3M Patient Warming technical service.

Displays

Condition	Cause	Action
"Ready" screen continues to display while sensor is adhered to the patient. 	Sensor not properly adhered to the patient.	Make sure the sensor is connected to the patient.
	Low patient temperature (below 29°C).	Press and hold the °C/°F button on the back of the control unit for five seconds to force the control unit into equilibration mode. The patient's temperature will then display.
	Control unit failure.	Discontinue use of unit. Contact 3M Patient Warming technical service.
"Running" screen does not appear on the control unit. 	Control unit may still be equilibrating.	Wait until the SpotOn control unit has finished equilibration. Continue use.
	Control unit failure.	Contact 3M Patient Warming technical service.
Patient temperature does not appear on the patient monitor. 	Control unit may still be equilibrating.	Wait until the SpotOn control unit has finished equilibration. Continue use.
	Monitor cable is not plugged in.	Make sure the monitor cable is plugged into the control unit and patient monitor.
	Cable failure.	• Replace monitor cable. • Contact 3M Patient Warming technical service.
	Control unit failure.	Contact 3M Patient Warming technical service after use.
The patient's temperature output on the control unit and patient monitor does not read the same value.	Cable failure.	• Replace monitor cable. • Contact 3M Patient Warming technical service.

Errors

Error Screen	Condition	Cause	Action
	E-1 through E-16, E-18 through E-99	Sensor not properly connected to the sensor cable.	Make sure the sensor is connected to the sensor cable.
		Sensor failure.	Replace sensor.
		Cable failure.	• Replace sensor cable. • Contact 3M Patient Warming technical service.
	E-17	Sensor failure.	Replace sensor.
		Cable failure.	• Replace sensor cable. • Contact 3M Patient Warming technical service.
		Control unit failure.	Discontinue use of the unit. Contact a biomedical technician.
	E-100 and up	Control unit failure.	Discontinue use of the unit. Contact a biomedical technician.

Section 5: General Maintenance, Storage and Service

Cleaning and Disinfecting Procedure 17
Storage 17
Service 17

Cleaning and Disinfecting Procedure

CAUTION:

- Do not immerse any of the devices or use a dripping wet cloth for cleaning. Moisture may seep inside the device and damage the electrical components and lead to incorrect temperature reporting.
- Do not spray cleaning solutions onto the control unit or into the sensor cable connector. Damage to the control unit or sensor cable connector may occur.

Cleaning the control unit and cable

Clean the SpotOn control unit on an as-needed basis or per facility policies and procedures for cleaning electronic equipment. Clean the sensor cable between each use.

1. Disconnect power supply from power outlet.
2. Use a slightly damp soft cloth moistened with a mild, nonabrasive cleaning solution to clean the device surfaces, cords, and cables. Avoid getting liquid into electronic ports.
3. Dry with a separate soft cloth.

Disinfecting the sensor cable

1. Clean the devices as described above.
2. Wipe down the control unit and cable using a damp soft cloth and 70% isopropyl alcohol solution. Avoid getting liquid into electronic ports.
3. Dry with a separate soft cloth.

Storage

Notice: Do not store the SpotOn control unit and system components in a wet or damp place. Damage to the electrical components may occur.

Store all SpotOn components at room temperature and in a dry place when not in use.

Service

All service must be performed by 3M Patient Warming or an authorized service technician. Call 3M Patient Warming Customer Service at 1-800-733-7775 for service information. Testing of the SpotOn system can be performed by 3M Patient Warming or call Customer Service for information about specific test procedures.

Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

Section 6: Technical Service and Order Placement

When you call for technical support 19
Technical service and order placement 19

When you call for technical support

Remember, we will need to know the serial number, software number and error code of your SpotOn control unit when you call us. The serial number label is located on the back of the control unit. (The firmware number displays on the control unit when the control unit is connected to a power outlet.)

Technical service and order placement

USA

TEL: +1-952-947-1200
+1-800-733-7775

FAX: +1-952-947-1400
+1-800-775-0002

Outside of the USA

Contact your local 3M Patient Warming representative.

Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

Section 7: Specifications

Physical characteristics 21
Electrical characteristics 22
Temperature characteristics 22
Performance characteristics 22
Environmental conditions 22

Physical characteristics

Dimensions of Control Unit
9.3 cm (3.7 in) high, extendable to 11.4 cm (4.5 in) high

7.1 cm (2.8 in) wide, 4.3 cm (1.7 in) deep

Weight of Control Unit
128 g (4.5 oz)

Dimensions of Sensor
4.1 cm (1.6 in) diameter, 0.5 cm (0.2 in) thick

Length of the Sensor Cable
400 cm (158 in)

Classification
MEDICAL—GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1; CAN/CSA-C22.2, No. 60601-1; ANSI/AAMI ES60601-1:2005 CSA-C22.2 No.601-1:08; EN60601-1; Control No.4HZ8

Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class II, Type CF, Defibrillation-Proof, Ordinary Equipment. Conforms to EN12470. Not suitable for use in the presence of flammable anesthetic mixtures with air or nitrous oxide.

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1, IEC 60601-1, and Canadian/CSA C22.2 No. 601.1. ANSI/AAMI ES 60601-1; 2005. EN60601-1. Classified under the Medical Device Directive as a Class IIb device.

Accuracy
25°C to 43°C ± 0.2°C

Sensor Material
Medical grade foam and adhesive

PET flexible circuit

Recommended Calibration Check
Every 12 months

Sensor Shelf Life
36 months

Digital Port
Serial output 0 [-12 to +12]

Monitor Cable Port
Provides a resistance that corresponds to a YSI-400 thermistor at the displayed temperature. It is electrically isolated from the SpotOn control unit.

Check the 3M™ SpotOn™ Temperature Monitoring System website to ensure you have the most recent version of this document. www.spotontemperature.com reorder #202052A

Electrical characteristics

External power supply
100-240 VAC, 50-60 Hz
Output; 5 VDC
Class II, double insulated medical grade

Maximum heating power
2 W

Temperature characteristics

Over-temperature cutoff
43°C - Skin thermistor reading

44.5°C - Heater thermistor reading

Performance characteristics

Equilibration time
3 minutes

Time response
Approximately three minutes

Measurement locations
Patient's lateral forehead above the orbital ridge

Measurement range
25°C - 43°C

Measurement readout
Celsius or Fahrenheit

Leakage current
CF classification. Meets leakage current requirements in accordance with UL 60601-1 and EN60601-1.

Environmental conditions

Ambient temperature range
10°C to 40°C (50°F to 104°F)

Storage and transport temperature range
-20°C to 60°C (-4°F to 140°F)

Store all components at room temperature and in a dry place when not in use.

Operating humidity
10 to 75% RH, noncondensing

Atmospheric pressure range
80 kPa to 106 kPa (12 PSI to 15 PSI)

Oxygen environment
The sensor only is suitable for use in the presence of an oxygen enriched environment.

CE 0086

Made in the USA by 3M Health Care.

3M is a trademark of 3M Company, used under license in Canada. SPOTON is a trademark of Arizant Healthcare Inc., used under license in Canada. ©2013 Arizant Healthcare Inc. All rights reserved.

EC REP 3M Deutschland GmbH, Health Care Business
Carl-Schurz-Str. 1, 41453 Neuss, Germany

3M Health Care, 2510 Conway Ave., St. Paul, MN 55144 USA
TEL 800-228-3957 | www.spotontemperature.com
202052A 04/13